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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,334	11/25/2003	Giovanna Galli	141483.00005-P1255US00	6523

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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,334	GALLI ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 3 Mar 2006.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) 6-7 and 9-13 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5 and 8 is/are rejected.

7)☒ Claim(s) 5 and 8 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 29 Dec 2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The election of species of piperacillin sodium without traverse filed March 3, 2006 has been recognized. Claims 1-5 and 8 will be examined on the merits. Claims 6-7 and 9-13 have been withdrawn from further consideration because they read on a non-elected species.

Specification

The disclosure is objected to because of the following informalities: The term "idroalcoholic" on page 7 should read "hydroalcoholic". Appropriate correction is required.

Claims

Claim Objections

1) Claim 5 is objected to because of the following informalities: The term "cetypiridinio" and should read "cetylpyridinium". Appropriate correction is required.

2) Claim 8 is objected to because of the following informalities: the term "cholramphenicol" should read "Chloramphenicol". Appropriate correction is required.

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-2 contains the trademark/trade name EUDRAGIT® RL and EUDRAGIT® RS. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a liquid methacrylate copolymer and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1-2, 4-5, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Friedman et al. (US 5,160,737).

Friedman et al. teach liquid polymer compositions to treat dental and dermatological conditions. The compositions comprise a liquid methacrylic acid copolymer and a pharmacological agent. The compositions form a film upon drying and releases the pharmaceutical agents over a period of time. Several polymer combinations were disclosed within the reference, a composition with Eudragit RL, one with Eudragit RS and one with a combination of Eudragit® RL and Eudragit® RS, which encompasses claims 1-2. The general procedure for making the polymer solutions included dissolving the polymer and therapeutic agent, cetylpyridinium chloride, in ethanol. After complete dissolution of these ingredients, additional components in aqueous solution were added, while continuously stirring. The ratio of film components to solvents (water/alcohol) was 1:3. In the water containing examples, the water makes up about 19% of the compositions (see example 19), which encompasses claim 4. Several therapeutic agents may be incorporated into the compositions, e.g., antibacterials chosen from the penicillins and ampicillins, erythromycin, tetracycline, clindamycin and chloramphenicol (which encompasses claim 8); antiseptics,

chlorhexidine and cetylpyridinium chloride; and hypersensitivity agents, potassium chloride and strontium salts, as recited in claim 5. These compounds are commercially available their pharmaceutical salts[1]. The reference anticipates the claims insofar as it teaches liquid polymer compositions comprising Eudragit® RL, Eudragit® RS or a combination of both and a therapeutic agent.

2) Claim 8 is rejected under 35 U.S.C. 102(e) as being anticipated by Mantelle et al. (US 6,562,363).

Mantelle et al. teach bioadhesive compositions in a flexible, finite form for topical application to skin or mucous membranes comprising a composition which results from an admixture of at least one PVP polymer, at least one bioadhesive and optionally a pharmaceutically acceptable solvent suitable for use with an active agent. The bioadhesive composition can either include an active agent incorporated directly in the composition, or a separate source of an active agent (see abstract). The pressure-sensitive adhesives that may be used in the compositions include acrylic adhesives, e.g., Eudragit® RS and RL. Eudragit® RS100 was used in Examples 79, 81 and 83, which also comprised dipropyleneglycol, making the composition a liquid composition as recited by the instant claims. The active agents that may be used in the delivery systems of the disclosed reference include antibacterial agents such as piperacillin[1].

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[1] Clindamycin and chloramphenicol are commercially available as their water soluble salt clindamycin Palmitate (http://www.webmd.com/drugs/drug-13718-Clindamycin+Palmitate+Oral.aspx?drugid=13718&drugname=Clindamycin+Palmitate+Oral), Chloramphenicol sodium succinate (http://www.rxlist.com/cgi/generic3/chloramphenicol.htm) and piperacillin sodium (http://www.rxlist.com/cgi/generic3/piperacillin.htm).

The disclosed compositions can be prepared by mixing the one or more bioadhesives, in powder or liquid form, PVP and active agent, with or without a pressure-sensitive adhesive, preferably in an appropriate volatile, lower molecular weight solvent. When a pressure-sensitive adhesive is used, preferably the volatile, lower molecular weight solvent is an organic solvent supplied with the pressure-sensitive adhesive, for example, the acrylic adhesive. The reference anticipates the instant claim insofar as it teaches liquid compositions comprising therapeutic agents such as piperacillin and a biocompatible polymer such as Eudragit® RS 100 in a liquid solvent.

3) Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Hasegawa et al. (US 4,701,320).

Hasegawa et al. teach compositions for treating periodontal disease, which comprise minocycline and a polymer such as methacrylate/chlortrimethylammoniumethyl methacrylate copolymer (Eudragit RS). The polymer comprises 0.5% to 10% of the polyhydric alcohol based composition (col. 5, tables at the bottom). The reference anticipates the instant claims insofar as it teaches composition comprising a liquid methacrylate copolymer Eudragit RS and a therapeutic agent for the treatment of oral cavity diseases.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (US 5,160,737) in view of Schneider et al. (US 4,980,170).

The primary reference is discussed above. The reference discloses Eudragit® RS and LS are water insoluble copolymer and if a water-soluble polymer is added to the combination, the properties of the film made by these polymer can be changed. The reference differs from the instant claim insofar as it does not disclose the Eudragit® RS/RL ratio ranges from 1.5:1 to 3:1.

Schneider et al. teaches pharmaceutical formulations and processes for their preparation, where the active ingredient is present in a retarded release dosage form. The pharmaceutical agent is coated with a membrane. The membrane comprises pharmaceutically acceptable polymers such as acrylic acid ester, methacrylic acid ester, copolymers of the acrylic and methacrylic acid esters, vinylacetates, modified cellulose derivatives etc. Particularly suitable polymers for the production of the membranes include, inter alia, copolymers of methacrylic acid and of methacrylic acid esters with

variable contents of quaternary ammonium groups, which determine the extent of the hydrophility and thereby also the permeability of the polymers. These polymers include copolymers with the trade name Eudragit® RL and Eudragit® RS. The two polymers are used in combination and the permeability of the Eudragit® RL/RS membrane can be adjusted at discretion by the mix ratio of the components. The mix ratio necessary for a desired release must be determined for the individual active substances in the manner known per se; normally it is within the limits of 20:80% by weight to 80:20% by weight Eudragit® RL to Eudragit® RS. The reference differs from the instant claims insofar as it does not disclose the polymers being in or a liquid composition comprising a therapeutic agent.

It would have been obvious to one of ordinary skill in the art to have used different Eudragit® RL and RS ratio combinations in the compositions of the primary reference motivated by the desire to make a liquid polymer containing composition that would release the therapeutic agent over a desired period of time as disclosed by the secondary reference.

Claims 1-5 and 8 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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